1. PRODUCT NAME

Duraphat 50 mg/mL Dental Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL suspension contains 50 mg sodium fluoride (5% w/v), equivalent to 22,600 ppm fluoride ion (22.6 mg of fluoride) in an alcoholic solution of natural resins.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dental Suspension

Brown/yellow, opaque suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Caries prevention by deep penetration with fluoride.
Desensitisation of sensitive teeth.

4.2 Dose and method of administration

Duraphat 50 mg/mL Dental Suspension is to be applied by the dental professional and not for self medication by the patient. For best results, remove excess plaque and dry teeth before applying Duraphat. Duraphat is applied as a thin layer to the most susceptible areas of dentition using a brush, probe or applicator. Refer to Section 6.6 for further pre-application recommendations.

Recommended dosage for single application:

For primary teeth: up to 0.25 mL (= 5.65 mg fluoride)

For mixed dentition: up to 0.40 mL (= 9.04 mg fluoride)

For permanent dentition: up to 0.75 mL (= 16.95 mg fluoride)

For caries prevention: the application is usually repeated every 6 months but more frequent applications (every 3 months) may be made.

For hypersensitivity: 2 or 3 applications should be made within a few days.

The patient should not brush the teeth or chew food for 4 hours after treatment.

Method of administration: For dental use.

4.3 Contraindications

Hypersensitivity to any ingredients of Duraphat.
Ulcerative gingivitis.
Stomatitis.
Bronchial asthma.

4.4 Special warnings and precautions for use

Application of Duraphat 50 mg/mL Dental Suspension to the whole dentition should not be carried out on an empty stomach.

On the day when Duraphat has been applied, no high dose fluoride preparations, such as fluoride gels, should be used. The administration of fluoride supplements should be suspended for several days after applying Duraphat. Prolonged daily ingestion of excessive fluoride may result in varying degrees of fluorosis.

4.5 Interaction with other medicines and other forms of interaction

The presence of alcohol (33.8% v/v) in the Duraphat formula should be considered.

4.6 Fertility, pregnancy and lactation

As this product contains 33.8% v/v of ethanol (each dose contains up to 0.2 g of alcohol), it is recommended to avoid its use in pregnant women and during lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Gastrointestinal disorders:

Very rare (<1/10,000): Stomatitis, gingivitis ulcerative, retching, oedema mouth and nausea may occur in sensitive (allergic) individuals

- if necessary, the dental suspension layer can easily be removed from the mouth by brushing and rinsing.

Skin and subcutaneous tissue disorders:
Very rare (<1/10,000): Irritation in sensitive individuals, angioedema

Immune System Disorders
Not known (cannot be estimated from the available data): Hypersensitivity.

Respiratory, thoracic and mediastinal disorders:

Very rare/Isolated report (<1/10,000): Asthma

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting and diarrhoea may soon occur after ingestion (within 30 minutes) and are accompanied by salivation, haematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight has been ingested, give calcium (eg milk) orally to relieve gastrointestinal symptoms and observe for medical assistance. For accidental ingestion of more than 15 mg fluoride/kg body weight, admit immediately to a hospital facility.

For advice on the management of overdose, please contact the Poisons Information Centre on 0800 764 766 (New Zealand).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Stomatological preparations, caries prophylactic agents

ATC code: A01A A01

Sodium fluoride applied topically after tooth eruption reduces caries by inhibiting demineralisation and promoting remineralisation of the tooth surface and by inhibiting the cariogenic microbial process.

Duraphat 50 mg/mL Dental Suspension also reduces dentinal hypersensitivity.

In the management of dental erosion associated with the frequent consumption of acidic beverages or gastric reflux, high concentration topical Fluoride agents are considered to be of value. Duraphat is at least as effective as 2% sodium fluoride Solution in inhibiting erosion *in vitro*.

5.2 Pharmacokinetic properties

After oral administration, fluoride absorption is rapid and extensive (90-100%) with peak fluoride plasma levels reached within 30 to 60 minutes after ingestion. Fluoride is widely distributed through the body and concentrates in bone and teeth. About 50% of fluoride is stored. Excretion is primarily through the kidneys with less than 10% being excreted in the faeces and less than 1% in sweat and saliva.

Duraphat covers teeth with a film of suspension which hardens in the presence of saliva and then persists, and which over the following hours causes fluoride to accumulate at a measurable depth in the tooth enamel.

Due to the slow release of fluoride, the exposure level would be well below the level that could cause toxic signs and symptoms in children.

Doses of fluoride associated with dental fluorosis and risk of bone fracture would be well above the expected exposure level from Duraphat dental suspension.

5.3 Preclinical safety data

The product is used under total control of the dental professional and the amount of fluoride introduced to the patient at one time is within acceptable safety limits. The recommended doses are up to 0.75 mL for permanent dentition. Treatment is recommended every 6 months or a maximum of every three months. For hypersensitivity, 2-3 applications are recommended within a few days. These levels of fluoride introduced are again within acceptable safety limits.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, carcinogenic potential and toxicity to reproduction and development.

The results of in vitro and in vivo genotoxicity studies are mixed. The significance of these findings to man are unclear.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
White beeswax
Shellac
Colophony
Mastic
Saccharin
Raspberry Flavour

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened: 3 years

After opening: use within 3 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container and special equipment for use, administration or implantation

1 x 10 mL Al tube with white plastic screw cap and sealing plug.

5 x 30 mL Al tube with white plastic screw cap and sealing plug.

6.6 Special precautions for disposal and other handling

- If necessary the teeth should be cleaned, especially at the sites most susceptible to caries. When groups of patients (e.g. in children's dentistry) are to be treated, they should clean the teeth themselves using a toothbrush.

- Clear one or two quadrants of excessive saliva. Dispense the correct amount of Duraphat from the tube onto an application/dosage pad. Apply to the teeth using a cotton applicator, probe or brush, painting and dabbing repeatedly to form a thin layer. Then treat the next quadrants in the same manner.

- It is advisable to begin by applying the varnish to teeth in the lower jaw before too much saliva collects. It may not be necessary to paint the lingual surfaces, as these are generally more caries-resistant. Duraphat should preferably be applied to those spots most susceptible to caries attack.

- The yellowish colour of Duraphat greatly facilitates its application and control. Duraphat sets in the presence of saliva. The effect of Duraphat depends upon the prolonged activity of the fluoride. The varnish film should not be removed prematurely. Patients should be advised not to brush their teeth or chew food for at least 4 hours after treatment. During this time, soft foods and liquids may be consumed.

- Instruments, clothing, etc. which comes into contact with Duraphat can be cleaned with alcohol.

7. MEDICINE SCHEDULE

Prescription Only Medicine

8. SPONSOR

Colgate-Palmolive Ltd
45 Knights Road
Lower Hutt
New Zealand

9. DATE OF FIRST APPROVAL

15 December 2021

10. DATE OF REVISION OF THE TEXT

Not applicable. This is the first version.